Artige®

Methylphenidate hydrochloride

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

WARNING: Important safety information is provided in a boxed warning in the full CMI. Read before using this medicine.

1. Why am I using Artige?

Artige contains the active ingredient methylphenidate hydrochloride. Artige is used to treat attention deficit hyperactivity disorder (ADHD). It is also used to treat narcolepsy, a sleep-attack disorder. For more information, see Section 1. Why am I using Artige? in the full CMI.

2. What should I know before I use Artige?

Do not use if you have ever had an allergic reaction to Artige or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.
For more information, see Section 2. What should I know before I use Artige? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Artige and affect how it works.
A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use Artige?

- ADHD (children only): Take 5mg once or twice daily at breakfast or lunch as per your doctor's instruction.
- Narcolepsy (adults only): Take 20 to 30 mg a day, depending on your doctor's instructions.
- Swallow whole or half tablet orally with water.

More instructions can be found in Section 4. How do I use Artige? in the full CMI.

5. What should I know while using Artige?

Things you should do	• Remind any doctor, dentist or pharmacist

	you visit that you are using Artige. • Take your medicine as directed by your doctor. • If you become pregnant while taking Artige, tell your doctor immediately
Things you should not do	• Do not stop using this medicine suddenly. • Do not change your dose without speaking to your doctor first.
Driving or using machines	• Artige may cause dizziness, drowsiness, blurred vision, or hallucinations (seeing or hearing things that aren't there) in some people. Be careful before you drive or use any machines or tools or ride a bike until you know how Artige affects you.
Drinking alcohol	• Alcohol may make the side effects worse. • Check to make sure food and other medicines taken do not contain alcohol.

Looking after your medicine	• Store tablets below 25°C. Keep your tablets out of the reach of children.

For more information, see Section 5. What should I know while using Artige? in the full CMI.

6. Are there any side effects?

Common side effects include headache, drowsiness, dizziness, sleepiness, shaking of the body, vomiting, mood changes, restlessness.
For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

WARNING: DRUG DEPENDENCE: Artige should be given cautiously to patients with a history of drug dependence or alcoholism. Chronic abusive use can lead to marked tolerance and psychological dependence with varying degrees of abnormal behaviour. Frank psychotic episodes can occur, especially with parenteral abuse. Careful supervision is required during withdrawal from abusive use since severe depression may occur. Withdrawal following chronic therapeutic use may unmask symptoms of the underlying disorder that may require follow up.

Artige®

Active ingredient: *methylphenidate hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Artige. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Artige.**

Where to find information in this leaflet:

1. Why am I taking Artige?
2. What should I know before I take Artige?
3. What if I am taking other medicines?
4. How do I take Artige?

5. What should I know while taking Artige?
6. Are there any side effects?
7. Product details

1. Why am I taking Artige?

Artige contains the active ingredient methylphenidate hydrochloride. Artige is a class of medicine that increases the activity of the brain.

Artige is used to treat Attention Deficit Hyperactivity Disorder (ADHD). It is also used to treat narcolepsy, a sleep-attack disorder.

2. What should I know before I take Artige?

Warnings

Do not take Artige if:

- you are allergic to methylphenidate hydrochloride, or any of the ingredients listed at the end of this leaflet.
- you have anxiety, tension or agitation
- you have Tourette's Syndrome (uncontrolled speech, body movements or tics) or a family history of Tourette's
- you have Glaucoma (increased pressure in the eye)
- you have an overactive thyroid or other thyroid problems

- you have heart problems - heart attack, irregular heartbeat, chest pain (angina), heart failure, heart disease or if you were born with a heart problem
- you have very high blood pressure (hypertension) or narrowing of the blood vessels (arterial occlusive disease, which can cause pain in the arms and legs)
- you have severe depression, eating disorder (anorexia) or other mental illness
- you have a tumour in the adrenal gland which can cause high blood pressure and headaches.

Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any other medical conditions such as depression, suicidal thoughts or behaviour, seeing or feeling things that are not there (hallucinations), unusual active or depressed mood (bipolar illness), aggressive behaviour
- have abnormal thoughts or are over-excited, over-active or un-inhibited
- have motor or verbal tics, uncontrolled speech or movements, repeated twitching or make repeated sounds or words, or if a family member has any of these
- have had fits/convulsions
- experience all of these problems: restlessness, tremor, sudden muscle contractions, abnormal high temperature, nausea, vomiting

- have high blood pressure (headaches, blurred vision, chest pain)
- have any other medical conditions such as current or previous heart problems or serious heart rhythm problems.
- have any other medical conditions such as weakening of the blood vessels in the brain, inflammation of the blood vessels, have had a stroke
- have a history of drug or alcohol abuse
- have eye problems, including increased pressure in your eye, glaucoma or trouble seeing close-up
- take any medicines for any other condition
- have painful or long-lasting erections
- have serious heart problems. You should be examined by a Heart Specialist before you take Artige.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Artige should not be taken in the first 3 months of pregnancy.

Do not breast feed if you are taking Artige.

Children under 6 years

- Do not use Artige in children under 6 years of age.

Children under 18 years of age

- Your doctor needs to take a detailed history and evaluation before you take Artige.
- Children may have slower growth if taking Artige for a long time.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Do not take Artige if:

- you are taking monoamine oxidase inhibitors (MAOI) or have taken this medicine in the last 2 weeks.

Tell your doctor or pharmacist if you are taking any of the following medicines:

- medicines that increase blood pressure;
- tricyclic antidepressants (treats depression);
- alpha 2 agonists (treat high blood pressure);
- oral anticoagulants (prevent blood clots);
- anticonvulsants (treat fits/seizures);
- medicines that treat mental illnesses (antipsychotics)
- phenylbutazone (treats pain or fever);

- that influence dopamine levels e.g. disease which affects movement (Parkinson's disease);
- that change the level of serotonin in the body such as sertraline or venlafaxine that are used to treat depression.

Tell your doctor or pharmacist if you are having an operation. Artige cannot be taken with anesthetics due to an increased risk of blood pressure.

Artige may give false positives in drug testing.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Artige.

4. How do I take Artige?

How much to take

- ADHD (children only): Start with 5 mg once or twice daily with gradual increases of 5 mg or 10 mg weekly, depending on your doctor's instructions.
- The highest recommended dose of Artige for children is 60 mg per day.
- Narcolepsy (adults only): the average dose is 20 to 30 mg a day, depending on your doctor's instructions.
- The highest recommended dose of Artige for adults is 60 mg per day.
- Follow the instructions provided and use Artige until your doctor tells you to stop.

When to take Artige

- Artige should be taken once or twice a day (for example at breakfast or lunch) as per your doctor's instructions.
- Doses should be taken 1 to 2 hours before the maximum effect is needed.
- Swallow tablet with water.
- Artige should be taken before 6pm as it can cause trouble sleeping if the dose is taken late.
- In some cases, sleeplessness occurs as the medicine wears off. Talk to your doctor about doses in the evenings.

If you forget to take Artige

Artige should be used regularly at the same time each day. If you miss your dose at the usual time, take it as soon as possible.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

- Do not take more medicine than your doctor tells you to; do not take it more often and do not use it for longer than your doctor tells you - this medicine can be addictive.

If you use too much Artige

If you think that you have used too much Artige, you may need urgent medical attention. You could experience vomiting, feeling uneasy or tense (agitation), headache, shaking (tremor), muscle twitching, irregular heartbeat, flushing, fever, sweating, dilated pupils, breathing problems, confusion, fits, muscle spasms, or red-brown urine (muscle breakdown).

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking Artige?

Things you should do

Take your medicine as directed by your doctor.

Make sure you keep any doctor's or specialist appointments as your doctor needs to assess your treatment periodically.

Call your doctor straight away if you:

- Have any chest pain, fainting or other possible heart problems.
- Have any abnormal thoughts, over-active/excited or uninhibited actions, aggressive behaviour, are seeing things.
- Have fits or tics
- Have eye problems
- Have slurred speech, confusion, loss of coordination, sudden numbness
- Have painful or long-lasting erections

Remind any doctor, dentist or pharmacist you visit that you are taking Artige.

Things you should not do

- Do not stop using this medicine suddenly.
- Do not change your dose without speaking to your doctor first.
- Keep all doctors and specialists' appointments.

Growth in children

- Some children taking Artige for a long time can have a slower than normal growth.

Medicines that raise serotonin

- For example sertraline, venlafaxine used to treat depression.

- If you feel restless, have tremor, abnormal high temperature, nausea, vomiting - stop using Artige.

Driving or using machines

Be careful before you drive or use any machines or tools or ride a bike until you know how Artige affects you.

Artige may cause dizziness, drowsiness, blurred vision, or hallucinations (seeing or hearing things that aren't there) in some people.

Drinking alcohol

Do not drink alcohol while taking Artige.

Alcohol can make the side effects worse. Check to make sure food and other medicines taken do not contain alcohol.

Taking stimulants

Stimulants including caffeine containing medications, foods, or beverages (e.g., energy drinks).

As these are also stimulants, using them together with Artige can increase side effects such as fast or irregular heartbeat and high blood pressure.

Sudden withdrawal

Do not suddenly stop taking Artige.

Stopping Artige suddenly can cause withdrawal effects - patients can feel depressed or long lasting over-activity.

Looking after your medicine

- Store below 25°C.

Follow the instructions on the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Problems of the brain, spinal cord and nerves: • Headache, dizziness • Drowsiness or sleepiness • Shaking of the body (tremor) • Emotional problems - excitement, restlessness • Rapid, extreme or unpredictable mood changes/mood swings • Nervousness • Being obsessed with one thing • Feeling aggressive • Feeling depressed • Trouble falling asleep, sleeping problems • Unusual active or depressed mood • Confusion, disoriented **Heart problems:**	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Less serious side effects	What to do
• A problem with heart rate or heart rhythm • Changes in blood pressure and heart rate (usually an increase) **Infections:** • Sore throat • Runny nose, nasal congestion • Cough • Sneezing • Fever **Eating problems:** • Decreased appetite • Decreased weight • Reduced weight gain **Mental illness:** • Grinding, gnashing, or clenching your teeth • Irritability • Feeling uneasy or worried - agitation • Nervousness	

Less serious side effects (continued)

Less serious side effects	What to do
Gut problems: • Nausea • Dry mouth • Stomach pain or upset • Feeling full soon after eating • Indigestion • Vomiting • Toothache • Diarrhoea • Constipation **Skin problems:** • Rash • Skin blisters • Itchy skin • Pink or red itchy rashes • Hair loss • Uncontrollable sweating **General problems:** • Feeling jittery • Bed wetting • Tiredness • Slow growth	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Less serious side effects	What to do
Blood-related problems: • Fingers feel numb, having pins and needles or turn blue/purple • Extreme coldness of hands or feet • Temporary muscle weakness, loss of skin sensation **Bones, joint problems:** • Joint stiffness or pain • Decreased ability to eat or speak • Locked jaw, trouble opening the mouth, tooth/neck/face pain • Muscle cramping • Muscle pain or twitch **Eye problems:** • Blurred eyesight • Double vision • Dilated pupils • Trouble seeing **Lung problems:** • Cough	

Less serious side effects	What to do
Body system which fights disease: • Swelling of the ears **Reproductive problems:** • Increased breast size in males	

Serious side effects

Serious side effects	What to do
Problems of the brain, spinal cord and nerves: • Twitching, jerking • Fingers or toes feeling cold, numb, tingling and changing colour • Fits • Muscle twitching or tics • Uncontrollable writhing of arms/legs, face or body **Heart problems:** • Very fast heart rate • Chest pain • Irregular beating of the heart	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Serious side effects	What to do
• Severe headache or confusion, weakness, unable to move (paralysis), trouble speaking **Mental illness:** • Thoughts of killing yourself • Seeing, hearing or feeling things that aren't there • High temperature and muscle stiffness • Drug abuse or dependence **Body system which fights disease:** • Sore throat with fever/ chills • Swelling of face, throat, lips, tongue; trouble breathing • Tiredness with more infections or bleeding **Blood problems:** • Bruising **Reproductive problems:**	

Serious side effects	What to do
• Prolonged erection, penis discomfort	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Artige contains

Active ingredient (main ingredient)	Methylphenidate hydrochloride

Other ingredients **(inactive ingredients)**	lactose, calcium phosphate, gelatin, magnesium stearate, purified talc and wheat starch
Potential allergens	Lactose, gluten, animal product

Do not take this medicine if you are allergic to any of these ingredients.

What Artige looks like

Artige tablets are immediate release white tablets that are scored and marked AB and CG on the reverse; packs of 100 tablets.

Australian Registration Number:

Artige tablet: AUST R 117306

Who distributes Artige

NOVARTIS Pharmaceuticals Australia Pty Limited

ABN 18 004 244 160

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Web site: www.novartis.com.au

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